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ANNEX A

CHAPTER I

Conditions for the approval of semen collection centres

Semen collection centres must:

1. be placed under the permanent supervision of a centre veterinarian;
2. have at least:
   (a) animal housing including facilities for the isolation of animals which have failed tests described in Annex B, Chapter II, or which show clinical signs of disease,
   (b) semen collection facilities including a separate room for the cleaning and disinfection or sterilisation of equipment,
   (c) a semen processing room which need not necessary be on the same site,
   (d) a semen storage room which need not necessarily be on the same site;
3. be so constructed or isolated that contact with livestock outside is prevented;
4. be so constructed that the animal housing and semen collection, processing and storage facilities can be readily cleaned and disinfected;
5. be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

CHAPTER II

Conditions relating to the supervision of semen collection centres

The collection centres must:

1. be so supervised that they contain only animals of the species whose semen is to be collected;
2. be so supervised that a record, file or computer record is kept of all porcine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record, file or computer record of all checks for diseases and all vaccinations carried out, giving also information from the disease/health file of each animal;
3. be regularly inspected by an official veterinarian, at least twice a year, at which time checks on the conditions of approval and supervision shall be carried out;
4. be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian;
5. employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;
6. be so supervised that:
   (a) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen;
   (b) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under conditions of the strictest hygiene;
   (c) all implements which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised prior to use;
   (d) products of animal origin used in the processing of semen — including additives or a diluent — are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;
   (e) storage flasks and transport flasks are properly disinfected or sterilised before the beginning of each filling operation;
   (f) the cryogenic agent used has not been previously used for other products of animal origin;
   (g) each collection of semen, whether or not it is separated into individual doses, is clearly marked in such a way that the date of collection of the semen and the breed and identification of the donor animal, as well as the name and the registration number of the centre, preceded by the name of the country of origin, where appropriate, in the form of a code,

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can be readily established; the characteristics and form of this marking will be established under the procedure laid down in Article 19.

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ANNEX B

CHAPTER I

Conditions applying to the admission of animals to approved semen collection centres

1. All animals admitted to a semen collection centre must:

   (a) have been subjected to a period of quarantine of at least 30 days in accommodation specifically approved for the purpose by the competent authority of the Member State, and where only animals having at least the same health status are present;

   (b) prior to their entering the quarantine accommodation described in (a) have been chosen from herds or holdings:

   — which are free of brucellosis in accordance with the Article 3.5.2.1 of the International Animal Health Code,

   — in which no animal vaccinated against foot and-mouth disease has been present in the preceding 12 months,

   — in which no clinical, serological or virological evidence of Aujeszky's disease has been detected in the preceding 12 months,

   — which are not situated in a restricted area defined under the provisions of the Community legislation due to the emergence of a disease in domestic pigs.

   The animals may not previously have been kept in any herd of a lower status

   (c) before the period of quarantine specified in (a) and within the previous 30 days, have been subjected to the following tests, performed in accordance with standards laid down in relevant Directives, with negative results:

   — a complement fixation test or a buffered brucella antigen test in respect of brucellosis (from 1 January 2001, the buffered brucella antigen test will be the only authorised test),

   — a serum neutralisation or an ELISA test using all the Aujeszky's disease viral antigens in the case of non-vaccinated pigs,

   — or an ELISA test for Aujeszky's disease G1 antigens in the case of pigs vaccinated with a G1 deleted vaccine,

   — an ELISA test or a serum neutralisation test for the presence of classical swine fever.

   With regard to brucellosis, if animals should prove positive, animals with negative results in the same holding are admitted in the quarantine accommodation after the confirmation of the brucellosis free status of the herds or holdings of origin of the positive reactors.

   The competent authority may give authorisation for the tests referred to in this paragraph to be carried out in the quarantine accommodation, provided that the results are known before the beginning of the 30 days quarantine period laid down in (a);

   (d) during the last 15 days of the period of quarantine of at least 30 days specified in (a), have been subjected to the following tests with negative results;

   — in respect of brucellosis, a complement fixation test or a buffered brucella antigen test (from the l January 2001 the buffered brucella antigen test will be the only authorised test),

   — a serum neutralisation or an ELISA test using all the Aujeszky's disease viral antigens in the case of non-vaccinated pigs, or an ELISA test for Aujeszky's disease G1 antigens in the case of pigs vaccinated with a G1 deleted vaccine.

   Without prejudice to the provisions applicable in cases where foot-and-mouth disease or other list A diseases are diagnosed, if any of the above-mentioned tests should prove positive, the animal must be removed forthwith from the quarantine accommodation. In the case of group quarantine, the competent authority must take all necessary measures to ensure that the remaining animals have a satisfactory health status before being admitted to the collection centre in accordance with this Annex.

   However, with regard to brucellosis when animals are positive, the following protocol is implemented:

   (i) the positive sera are subjected to a sero-agglutination test as well as the test mentioned at the first indent above which has not been carried out,

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(ii) an epidemiological survey is carried out on the holdings of origin of the reacting animals,

(iii) on the positive animals, a second series of tests (buffered brucella antigen test, sero-agglutination, complement fixation) is carried out on samples collected more than seven days after the first collection.

The suspicion of brucellosis will be confirmed or ruled out in the light of the results of the survey carried out on the holdings of origin and the comparison of the results of the two series of tests.

When the suspicion of brucellosis is ruled out, the animals negative to the first brucellosis test can be introduced into the centre. Animals positive to one test may be accepted if they answer negatively to two series of tests (buffered brucella antigen test, sero-agglutination, complement fixation) carried out with an interval of at least seven days.

2. All tests must be carried out in a laboratory approved by the Member State.

3. Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All animal movements, both in and out, must be recorded.

4. No animal admitted to the semen collection centre may show any clinical sign of disease on the day of admission; all animals must, without prejudice to paragraph 5, have come directly from quarantine accommodation as referred to in paragraph 1(a) which, on the day of consignment, officially fulfils the following conditions:

(a) it is not situated in a restricted area defined under the provisions of the Community legislation due to the emergence of a disease in domestic pigs;

(b) ►**M2** no clinical, pathological or serological evidence of Aujeszkys disease has been recorded for the past 30 days ◄;

5. Provided that conditions laid down in paragraph 4 are satisfied and the routine tests referred to in Chapter II have been carried out during the previous 12 months, animals may be transferred from one approved semen collection centre to another of equal health status without quarantine or testing if transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been disinfected before use.

6. In case of trade between Member States, animals will be accompanied by an animal health certificate in conformity with the model 2 in Annex F to Directive 64/432/EEC, the disinfection of the mean of transport being certified in section C, point 4, as one of the following additional guarantee, corresponding to their status:

— animals come directly from a semen collection centre complying with Directive 90/429/EEC;

— animals come directly from a quarantine accommodation and comply with the seen collection centre admission conditions provided in chapter 1 of Annex B to Directive 90/429/EEC;

— animals come directly from a holding where they were undergoing the pre-quarantine admission protocol and comply with the quarantine admission conditions provided in Chapter I points (1)(b)(c) and (2) of Annex B to Directive 90/429/EEC.

CHAPTER II

Compulsory routine tests for animals kept at an approved semen collection centre

1. All animals kept at an approved semen collection centre must be subjected to the following tests with negative results:

(a) a serum neutralisation or an ELISA test using all the Aujeszky's disease viral antigens in the case of non-vaccinated pigs,or an ELISA test for Aujeszky's disease G1 antigens in the case of pigs vaccinated with a G 1 deleted vaccine;

(b) in respect of brucellosis, a complement fixation test or a buffered brucella antigen test (from the 1 January 2001 the buffered brucella antigen test will be the only authorised test);

(c) an ELISA test or a serum neutralisation test for the presence of antibodies of classical swine fever.

These tests shall be carried out either:

on all animals when leaving the centre, but not later than l2 months after admission where they have not left the centre before this time. The sampling may be carried out in the abattoir;

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or

on 25 % of the animals in the centre are tested every three months.

In this case, the centre veterinarian shall ensure that the samples taken are representative of the total population of the centre, in particular with respect to age group and boar accommodation. Furthermore, the centre veterinarian shall also ensure that all animals are tested at least once during their stay at the centre and at least every 12 months if their stay exceeds a year.

2. All tests must be carried out in a laboratory approved by the Member State.

3. If any of the above tests should prove positive, the animal must be isolated and the semen collected from it since the last negative test may not be the subject of intra-Community trade.

Semen collected from each animal at the centre since the date of that animal's last negative test shall be held in separate storage and may not be the subject of intra-Community trade until the health status of the centre has been re-established.

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ANNEX C

Conditions which semen collected at approved centres must satisfy for the purposes of intra-Community trade

1. Semen must be obtained from animals which:

   (a) show no clinical signs of disease on the day the semen is collected;

   (b) have not been vaccinated against foot-and-mouth disease;

   (c) satisfy the requirements of Annex B, Chapter I;

   (d) are not allowed to serve naturally;

   (e) are kept in semen collection centres which must not be situated in a restricted area designated under the provisions of the Community legislation relating to contagious diseases in domestic pigs;

   (f) have been kept in semen collection centres which, during the 30-day period immediately prior to collection, have been free from Aujeszky's disease.

2. An effective combination of antibiotics, in particular against leptospires and mycoplasmas, must be added to the semen after final dilution or to the diluant. In case of frozen semen, antibiotics must be added before the semen is frozen.

   This combination must produce an effect.at least equivalent to the following dilutions:

   not less than: 500 µg streptomycin per ml final dilution
   500 IU penicillin per ml final dilution
   150 µg lincomycin per ml final dilution
   300 µg spectinomycin per ml final dilution.

   Immediately after the addition of the antibiotics the diluted semen must be kept at a temperature of at least 15 ºC for a period of not less than 45 minutes.

3. Semen for intra-Community trade must:

   (a) be stored as laid down in Chapters I and II of Annex A prior to dispatch;

   (b) be transported to the Member State of destination in flasks which have been cleaned and disinfected or sterilised before use and which have been sealed prior to dispatch from the approved storage facilities.

4. Member States may refuse admission of semen from collection centers where boars vaccinated against Aujeszky's disease are admitted, to their territory or to a region of their territory, when it has been recognised as free of Aujeszky's disease in accordance of Article 10 of Directive 64/432/EEC.